Remarks

Claims 11, 12, 14-27, and 29-32 are currently pending in the instant patent application. With this response, Applicant's instantly claimed invention is directed to a method of producing a tablet including live bacteria comprising the steps: (a) mixing at least one strain of said live bacteria with at least one fructose oligosaccharide to form a mixture and (b) pressing said mixture into a tablet employing a force sufficient to form said tablet having a friability of between 0.1 and 1.0 while maintaining at least about 60% viability of said bacteria following the compression.

Claim Rejection – 35 U.S.C. § 112 First Paragraph

The Examiner has rejected claims 11, 12, 14-27, and 29-32 under 35 U.S.C. § 112 first paragraph, as not containing subject matter which was described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner asserts that the claim limitations of having a friability range "between 0.1 and 1.0" and bacterial viability of "at least 60%" (claims 11, 16, 27, and 28) and the additional limitation of having a friability range of "between 0.3 and 0.5" (claims 27-32) lack support from the specification. However, the specification (page 3, lines 22-32) provide the necessary antecedent basis for the rejected claims:

> Due to this new composition, the punching pressure for the tablet making maybe reduced by up to 50% compared to conventional tablet punching methods without any reduction of the friability. This friability according to the invention will be (0.3-0.5) which is to be compared with the reference values which are accepted according to GMP (Good Manufacturing Practice) which are within the range of 0.1-1.0.

this is a good mat showing

The Federal Circuit has held that the written description requirement is satisfied by the patentee's disclosure of "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). In the instant application, the inventor recites sufficient information, a 40% reduction in cfu and the data in Example 1 concerning "a recipe having an active substance and tablet filling material." Thus, it is clear to one of ordinary skill in the art that the inventor of the instant application not only has possession of the claimed invention but also described to one of skill in the art the compositions of the tablets made by the claimed method, thereby satisfying the written description requirement.

The Examiner argues that merely disclosing the method for constructing a single compound, one that sits at one of the endpoints of a range, is insufficient to show that the inventor possessed the entire range at the time of filing. However, it is simply not required that the written description disclose every possible combination of materials that would lie within the claimed range. "The written description requirement does not require identical descriptions of claimed compounds, but it requires enough disclosure in the patent to show one of skill in this art that the inventor 'invented what is claimed.'" *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000) (internal citation omitted).

It is clear from the specification that Applicant was in possession of a method of providing at least 60% viability of bacteria following compression of the ingredients into tablets, while maintaining friability between 0.1 and 1.0. Disclosure of the

0.3

claimed method of producing this compound teaches one skilled in the art the capacity of constructing additional compounds that lie within the claimed range. Likewise, it shows to individuals skilled in the art that the inventor was in possession of the claimed invention, namely the method for producing tablets within the claimed range, at the time of the application.

The example claimed in the specification (Example 1, page 4, lines 21-34) teaches that with the materials stated a punching machine will create a tablet with 60% viability of the bacteria and a friability of 0.3. It would be obvious to one skilled in the art that reducing the pressure of the punching machine would cause an increased viability (greater than 60%) because the bacteria would not be exposed to such extreme conditions. Moreover, an increased friability (greater than 0.3) would be obtained because the materials would not be as densely packed. Although the exact values are not disclosed in the specification, routine experimentation by a skilled artisan would assuredly result in the creation of additional compounds falling within the claimed ranges. Moreover, one skilled in the art, by examining the written description, would know that the inventor was in possession of the claimed invention at the time the application was filed.

what about less than 0.3, will viability be still at least 60%?

The fact that routine experimentation is required for one skilled in the art to make or use the claimed invention does not render the claims invalid. "A patent must 'contain a description that enables one skilled in the art to make and use the claimed invention. . . . 'An invention need not, however, explain every detail since he is speaking to those skilled in the art.'" *DeGeorge v. Bernier*, 768 F.2d 1318 (Fed. Cir. 1985) *citing In re Howarth*, 654 F.2d 103 (CCPA 1981). In *Atlas Powder v. E.I. du Pont de Nemours & Co.*, the Federal Circuit held that even though the

specification listed elements that could form thousands of end products, some of which may not be operative, the description was still enabling. 750 F.2d 1569 (Fed. Cir. 1984). Merely altering the pressure and using the materials disclosed in Example 1, would produce a vast array of tablets that meet the ranges disclosed in the rejected claims. Additionally, marginal changes to the components of Example 1 would also result in variations along the range claimed by the Applicant. These changes would be obvious to one skilled in the art at the time of the instantly claimed invention and would not require undue experimentation. Moreover, the written description would have demonstrated to those skilled in the art that the inventor was in possession of the claimed invention at the time of the application. Since the written description proves that the inventor was in possession of the claimed invention at the time of the application and since the written disclosure is enabling, Applicant respectfully submits that claims 11, 12, 14-27, and 29-32 are now in condition for allowance.

Claim Rejection - 35 U.S.C. § 112 Second Paragraph

The Examiner has rejected claims 11, 12, 14-27, and 29-32 under 35 U.S.C. § 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner bases her rejection on the use of the phrase "a force sufficient" as stated in claims 11, 16, 22, and 27-32.

The "force" as described in claims 11, 16, 22, and 27-32 is properly defined by the specification. The tablets of the instantly claimed invention are formed on a "tablet punching machine." (see page 1, lines 14-16). This tablet punching machine uses pressure to form tablets. (see page 1 lines 14-20). Thus the use of "force" has proper antecedent basis from the specification.

The sufficiency of the force also contains a proper antecedent basis from the claims. "[T]he punching pressure for the tablet making maybe reduced by up to 50% compared to conventional tablet punching methods." (page 3, lines 22-24). One skilled in the art would know the "punching pressure" for "conventional tablet punching methods." One skilled in the art would know that altering the punching pressure would alter the characteristics of the tablet, specifically the viability of the bacteria and the friability of the tablet.

Under M.P.E.P. § 2173.02, "[i]f the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph would be appropriate." (internal citation omitted). However, defining every possible "sufficient force" is simply not required. "Not every last detail is to be described, else patent specification would turn into production specification, which they were never intended to be." *In re Gay*, 309 F.2d 769, 774 (CCPA 1962). Disclosing all of the possible "sufficient forces" that would be suitable to creating tablets according to the claims would simply not be practical or possible. The type and proportions of the materials used, the desired viability of the bacteria, and the desired friability of the tablet are determinative of how much force is sufficient. It is enough that one skilled in the art would know from the language of the claims and the specification what the limits of the claim are: "One skilled in the art would know how to program a microprocessor to perform the necessary steps described in the specification. Thus, an inventor is not required to describe every detail of his invention." *In re hayes Microcomputer Products, Inc. Patent Litigation*, 982 F.2d 1527, 1534-35 (Fed. Cir. 1992).

With regards to the instantly claimed invention, one skilled in the art would either know implicitly, or would be able to modify the pressures of their tablet punching machines to determine, what sufficient force would be required to create tablets falling within the range of viability and friability of the instantly claimed invention, especially when the specification gives the general suggestion of 50% less than the standard pressure of tablet punching machines. Thus, one skilled in the art would know the "metes and bounds of the claim." M.P.E.P. § 2173.02. Therefore, the use of the phrase "force sufficient" is not indefinite.

Since the claims point out and distinctly claim the subject matter Applicant regards as his invention, the rejected claims are not indefinite. Therefore, Applicant respectfully submits that claims 11, 12, 14-27, and 29-32 are now in condition for allowance.

Claim Rejection - 35 U.S.C. § 103

The Examiner has rejected claims 11, 12, 14-27, and 29-32 under 35 U.S.C. § 103(a), as being obvious over U.S. Patent 5,531,989 ("Paul") in view of U.S. Patent 4,806,368 ("Reddy"), in further view of U.S. Patent 5,536,526 ("Virtanen"), in further view of U.S. Patent 5,422,346 ("Mitchell"), in further view of U.S. Patent 4,396,631 ("Adachi") and in further view of U.S. Patent 4,021,545 ("Nair"). The Examiner asserts that combining Paul's disclosure of a method of producing compositions with live lactic bacteria with fructose oligosaccharide or inulin, Virtanen's disclosure of teaching tableting techniques related to friability, Reddy's disclosure of a method for making tablets with live bacteria including *Lactobacillus* and *Bifidobacterium* and other additives such as dietary fibers, calcium phosphate, cellulose and others, Paul's disclosure of inulin, Mitchell's disclosure of fructose or inulin, Adachi's disclosure of mixing live bacteria

with polysaccharides, and Nair's disclosure of producing tablets with inulin and other additives such as starch or calcium diphosphate, would make obvious the present invention i.e., a method of producing a tablet including live bacteria comprising the steps: (a) mixing at least one strain of said live bacteria with at least one fructose oligosaccharide to form a mixture and (b) pressing said mixture into a tablet employing a force sufficient to form said tablet having a friability of between 0.1 and 1.0 while maintaining at least about 60% viability of said bacteria following the compression.

Applicant respectfully submits that the Office Action fails to establish a *prima facie* case of obviousness under the standard established by M.P.E.P. § 2142, which states:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicants' disclosure.

Applicant respectfully submits that the obviousness rejection does not meet the first or third requirements. Numerous cases illustrate the common theme that there must be a suggestion in the prior art for two references to be combined to determine whether a claimed invention is obvious under said prior art references. In *Carella v. Starlight Archery*, the Federal Circuit states "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some

teaching, suggestion or incentive supporting the combination." 804 F.2d 1091 (Fed. Cir. 1986). Particular disclosures made in prior art references cannot merely be strung together to invalidate claims due to obviousness: "it is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combinations; there must be some teaching, suggestion, or incentive to make the combination made by the inventor." *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931 (Fed. Cir. 1990), *cert. denied* 498 U.S. 920 (1990).

Applicant respectfully submits that there is no teaching or suggestion in the prior art that the aforementioned references can be combined. There is nothing within the cited references that would suggest or motivate an individual to pick and choose disparate elements from the numerous references and arrange them to form the instantly claimed invention. Therefore the obvious rejection does not satisfy the first criteria for establishing a *prime facie* case of obviousness under M.P.E.P. §2143.01.

Moreover, the cited references, even if combinable, do not teach, suggest, or motivate one skilled in the art at the time of the invention to create a method of preparing live bacteria tablets by using fructose oligosaccharides as a supporting substance wherein said tablets have at least a 60% viability and a friability of between 0.1 and 1.0 following the compression. Therefore, the office action fails to satisfy the third criteria for establishing a *prime facie* case of obviousness under M.P.E.P. §2143.01 because the combination does not disclose "all the claim limitations" of the rejected claims.

Looking to the individually cited references, the Examiner cites Paul for disclosing a product containing live lactic bacteria and inulin and packaging it in a suitable container. She admits

that Paul is silent on the issue of friability of the final product. There is a reason for Paul's silence. The "suitable container" cited by the Examiner was by no means intended to include compression into the standard tablet form. The following recitation from Paul explains more fully what is meant by a "suitable container": "The agglomerated material is then packaged in a suitable container. Just prior to consumption, the dry composition is reconstituted with water, juice, or the like to result in a smooth liquid composition that can be consumed orally." (Paul column 13, lines 48-51). Paul relates to a dissolvable mass, not a solid and swallowable tablet. Moreover, there is no teaching or suggestion in Paul that the compositions form a solid tablet. In fact, forming the agglomerated material of Paul into a tablet with friability between 0.1 and 1.0 would likely render the tablet inoperable for purposes of the Paul patent *i.e.*, dissolving the material in a fluid. There is also no suggestion contained within this patent to combine it with any of the other patents cited by the Examiner. The fact that Paul is directed to a dissolvable mass would indicate that it is not analogous art with those references concerning formation of pills and tablets, and is specifically not analogous art with the instantly claimed invention.

The Examiner states that the Virtanen patent discloses a tablet with a friability of between 0% and 3%. However, the scope of the Virtanen patent is directed towards forming a tablet comprised of xylitol, for food or drug purposes. (Virtanen column 2, lines 61-63). The reason xylitol is used is that it has a "physical cooling effect" on the mouth without causing the side effect of tooth decay. (Virtanen column 2, lines 16-19, 42-44). Although Virtanen mentions that friability between 0% and 3% is desirable, it does not teach or suggest combination of this range

with tablets containing live bacteria. Nor does Virtanen teach or suggest a combination of ingredients, specifically including fructose oligosaccarides, that would make production of tablets within the friability ranges of 0.1-1.0 and 0.3-0.5 and with a viability of bacteria greater than 60% possible.

The Examiner asserts that Reddy discloses hard tablets containing live bacteria mixed with dietary fibers, calcium phosphate, cellulose, etc. The Examiner further asserts that Reddy discloses a viability of the bacteria in excess of 60%. (Reddy column 9, Table IV). However, Table IV of Reddy relates to comparing the shelf-life in terms of the bacterial viability of a tablet form to a powder form, specifically comparing the effect of the lack of oxygen in the tablet form to the abundance of oxygen in the powdered form. Reddy is silent as to when the initial population of the bacteria was determined, *i.e.*, before or after the tablet formation process, "[t]he initial population of *L. acidophilus* was determined in both the preparations" (Reddy column 9, lines 33-35). It would make little sense to determine the effect of the removal of oxygen on the viability of the bacteria if the bacterial population of the tablets was determined before their formation. This would simply add an additional variable, the heat and pressure of tablet formation, into the equation.

Additionally, Reddy is silent concerning the friability of the tablets. One of the key aspects of the instantly claimed invention is that the method claimed produces a tablet with a high viability rate of the bacteria but that it also maintains friability between 0.1 and 1.0. The instantly claimed invention accomplishes this through the use of fructose oligosaccarides, such as inulin, as the supporting substance, which the Examiner admits is not disclosed by Reddy. The use of fructose oligosaccharides is not a trivial

aspect of the instantly claimed invention. The problem with prior versions of live bacteria containing tablets is that they either had low bacterial viability or they used less pressure in the tablet forming process causing a greater friability. The use of fructose oligosaccharides as the so-called supporting substance allows the tablets to be formed by the tablet punching machine at a lower pressure and thus lower heat, while still maintaining the hardness and not decreasing the friability of the tablet. Assuming that Reddy's Table IV refers to pre-formation bacterial populations, which is highly speculative, the fact that the patent fails to disclose the hardness and friability of the tablets is indicative of Reddy's failure to maintain the production and quality standards as disclosed in the instantly claimed invention.

The Examiner again cites Paul to supplement Reddy's failure to disclose the use of fructose oligosaccharides. However, the disclosure of the use of inulin by Paul is not related to the instantly claimed invention. As stated above there is no suggestion in either Paul or Reddy to combine the two and lacking such suggestion to combine, it is improper to consider them together. Moreover, the use of inulin in Paul to form a dissolvable mass would not provide motivation to use fructose oligosaccharides as a supporting substance in the formation of swallowable tablets. The purpose of the fructose oligosaccharides in the instantly claimed invention is to decrease the pressure at which the tablets are formed. This decreases the heat to which the tablets are subjected and raises the viability of the bacteria. Thus, contrary to the Examiner's assetion neither Reddy, Paul nor a combination of the two would teach or suggest this application.

The Examiner asserts that Mitchell discloses the use of fructose oligosaccharides or inulin in the production of tablets

and teaches that inulin can be compressed into tablets without the need of additional tableting materials. The Examiner, also cites Mitchell as disclosing the use of inulin as a growth promoting substrate of lactic bacteria and that pathogenic bacteria cannot utilize inulin. However, Mitchell is directed towards a method of extracting inulin from plants and delivering it to the intestinal tract. (Mitchell abstract). Mitchell is not directed towards a method of tablet production, specifically tablet production wherein the tablets contain living bacteria, of which at least 60% survive the tablet making process.

Although Mitchell discloses the formation of tablets composed entirely of inulin, it fails to disclose the formation of tablets composed of inulin and bacteria, the heart of the instantly claimed invention. Moreover, the mere disclosure that tablets of pure inulin can be ingested to promote the growth of *Bifidus* in the gut does not teach or suggest a method for creating tablets composed of fructose oligosaccharides that have a bacterial viability of at least 60% and friability between 0.1 and 1.0. Furthermore, Mitchell does not suggest the combination with any of the other disclosed references.

The Examiner asserts that Adachi discloses a method for producing tablets with live bacteria using a polysaccharide and other materials suitable for tablets, and then pressing the mixture with a force sufficient to form tablets with viable bacteria. The creation of tablets containing living bacteria is nothing new. In fact, this is disclosed in the instant patent application. (pages 2-3). The novel aspect of the instantly claimed invention is the use of fructose oligosaccharides to create a tablet material which, upon tablet formation, has a bacteria viability rate of at least 60%, a suitable hardness, and friability between 0.1 and 1.0. The

Examiner admits that Adachi fails to disclosure the use of fructose oligosaccharides or inulin in the tablet mixture. This ingredient is one of the key elements of Applicant's claims. It is the use of this ingredient that allows a reduced pressure in the tablet formation process, thus allowing the tablets to have a suitable friability while maintaining high levels of bacterial viability. Additionally, there is nothing within Adachi, which teaches or suggests combining a fructose oligosaccharide with living bacteria to create a tablet having a high viability of the bacteria without sacrificing friability.

Moreover, although the Examiner cites Adachi's disclosure of high bacterial viability after formation of the tablets in Example 1, Example 1 merely discloses an after formation bacterial population of $2.8x10^8$ and a population of $8.2x10^7$ after three months. (Adachi column 4, line 40 to column 5, line 9). This does not tell us what the bacterial population was *before* the formation of the tablets. Without this starting point it is impossible to determine what the viability *rate* is of bacteria formed under Adachi.

The purpose of the instantly claimed invention is to develop tablets that have a high viability rate of live bacteria when undergoing the tablet formation process. Merely disclosing the number of living bacteria after tablet formation without disclosing the number of living bacteria before tablet formation gives no insight into maximizing the viability rate of bacteria undergoing tablet formation. The tablet bacterial count is irrelevant to the instantly claimed invention and thus we respectfully do not agree with the Examiner's improper comparison of such a bacterial count in Adachi with Applicants claimed invention. When we compare however, the number of living bacteria in the example of the

instantly claimed invention (which is at the low end of the claimed viability range) with Example 1 of Patent A, we find that the instantly claimed invention has a full 50% more living bacteria after tablet formation than does Example 1 ($3x10^8$/g vs. $2x10^8$/g). (page 4 and Adachi column 4, lines 61-63).

The Examiner states that Nair discloses a method for producing tablets containing inulin and other additives such as starch or calcium diphosphate. However, Nair does not teach or suggest combining tablets containing inulin and other additives with living bacteria. Moreover, Nair does not teach or suggest combination with any of the other cited references.

None of the references cited disclose a method for producing tablets which have a viability rate of at least 60%. Moreover, none of the references cited teach or suggest a method for producing tablets which have a viability rate of at least 60% while still maintaining acceptable levels of hardness and friability. While some of the references disclose the creation of inulin tablets and others disclose combining inulin tablets with other additives such as starch or calcium diphosphate, not one teaches or suggests that tablets containing living bacteria should be formed from fructose oligosaccharides because such tablets can be formed at lower pressures thus allowing for greater bacterial viability while still maintaining acceptable friability.

Since the office action fails to meet the first or third criteria for establishing a *prima facie* case of obviousness Applicant respectfully submits that claims 11, 12, 14-27, and 29-32 are in condition for allowance.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited. If however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested response, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: June 13, 2003

Respectfully submitted,

By Gerard P Norton

Gerard P. Norton
Registration No.: 36,621
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorneys for Applicant